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April 6, 2000

FOOD AND DRUG ADMINISTRATION
Dockets Management Branch HFA-305
12420 Parklawn Dr., Room 1-23
Rockville, MD 20857
Attn: Docket Number 95S-0158

Subject: BB-IND 7371
Protocol AHS02: Disclosure of Study Results, and Additional Community Consultation Documentation

To Dockets Management Branch:

Reference is made to our Investigational New Drug Application for Humanized Monoclonal Antibody Hu23F2G for Hemorrhagic Shock, BB-IND 7371, which was originally submitted to the FDA Office of Therapeutics Research and Review on October 28, 1997. We also refer to:

i) Protocol AHS02, entitled "Phase 2B Safety and Efficacy Study of Hu23F2G in Subjects with Hemorrhagic Shock," which was included in the original submission; and

ii) The guidelines described in 21 CFR §312.54(a) which require that Institutional Review Board (IRB) information concerning public disclosure be submitted to Docket 95S-0158, for clinical investigations involving an exemption from informed consent under 21 CFR§50.24.

The purpose of this submission is to provide documentation (21 CFR§50.24(a)(7)(iii)) concerning public disclosure following completion of Protocol AHS02. The individual site's IRB has approved the advertisement included in this submission to apprise the communities and researchers of the completed study. The advertisement includes demographic characteristics of the research population and the study results. The advertisement was run in the Houston Chronicle on both Monday, March 6, 2000 and Wednesday, March 8, 2000.

Listed below is the IRB which governed the site that conducted Protocol AHS02. Copies of the advertisements for disclosure of study results as approved by this IRB are included in this submission.

95S-0158

Sup 23

Committee for the Protection of Human Subjects
University of Texas – Houston Medical School
6431 Fannin, JFB G.700
Houston, Texas 77030

If you have any comments or questions regarding this submission, please do not hesitate to contact me at (425) 415-2297.

Sincerely,

Jeff Hesselberg, M.B.A.
Associate Director, Regulatory Affairs

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or plane

Calif. – A South-737 jet, carrying 137 d five crew, skidded a runway Sunday arby street, barely yron gas station. d co-pilot and a pas-ightly injured when rom Las Vegas to the runway and hit ar.

gear collapsed, a r the Federal Avia-tration said, but it whether this was the of the accident.

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– Officials for the id Sunday they will ompany's most re-offer on engineers al workers, whose en on strike against giant for 3½ weeks. for 17,000 striking ussed the action as get workers to cross nd called it an unfair e.

cials said employees receive pay raises the first year of the eb. 26 contract offer. rkers will get a guar-num 2 percent wage n a pool representing ddition crease to selec

march held

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n clogged roads lead-nial Old San Juan, a walled city.

fter rampage

BURG, Pa. – Sunday ces focused on heal-termath of a shooting which three people nd two were critically

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ged his parishioners the victims and their

ged them to pray for Ronald Taylor, who harged with criminal thnic intimidation – ua's term for a hate ggrava ssault, ar-using strophe.

werball pot

NES, Iowa – Holders old in three states will urday's $150 million ckpot, lottery officials

tickets were sold in nnesota and Missouri, fficials reported. will have the option of

Professional film made to help condemned man

NASHVILLE, Tenn. (AP) – Members of the music and film industry have donated their expertise to a man sentenced to die for killing a police officer. They are producing a video with the single goal of persuading the governor to grant clemency to the condemned man.

The state's parole board has viewed videos in other cases, typically from crime victims who don't want to testify in person, said Donna Blackburn, the board's executive director.

But this video is different.

Amid emotional testimony and professionally arranged photos and news footage, narrator Anastasia Brown – a music talent manager married to one of the city's most successful record producers, MCA Nashville President Tony Brown – asks Gov. Don Sundquist to show "grace and mercy" in his consideration of the case of Philip Workman.

Workman, 46, is to be executed April 6 for fatally shooting Memphis police Lt. Ronald Oliver in 1981.

Workman has a parole board hearing Thursday, and Sundquist has said he will wait for a recommendation from the board before considering clemency.

"Hello, my name is Anastasia Brown," the video begins. "I'm not a lawyer or an expert. I'm just a really concerned citizen."

Brown then makes the defense team's case.

Workman's lawyers say he had poor legal representation at trial, that ballistics evidence suggests someone else fired the shot that killed Oliver, and that a key prosecution witness now says he never saw the shooting.

"We can crystallize a lot of our issues on the tape, so that we don't have to spend a lot of time at the hearing explaining our evidence," said Jefferson Dorsey, one of Workman's lawyers.

The 25-minute tape includes narration, quotes from court rulings, crime scene photos, television news footage and recent interviews with Workman, his daughter, the shooting victim's daughter and three of the original trial jurors. All ask that he be spared from execution.

The video also has footage of Harold Davis, the prosecution witness who told Workman's lawyers that Memphis police coached him to give false testimony.

The video was directed by Trey Fanjoy and edited at Ground Zero, a Nashville production facility.

Such videos have been used in clemency hearings in other states, Dorsey said, but the technique is new to Tennessee, which has not held an execution since 1960.

Trauma Study Results

The University of Texas - Houston Medical School/Hermann Hospital recently participated in a research study to examine an investigational drug that may help severely injured persons. One very important part of this study was that waiver of individual or family consent to participate in this study was possible. Informed consent traditionally must be obtained from a patient or from the patient's responsible relatives before that patient may be entered into a research study. The details of the research study are clearly explained and any questions are asked and answered, and everyone understands that they may agree to be in the study or not. The Federal Food and Drug Administration (the FDA) regulates research studies and, occassionally, permits waiver of consent. The Committee for the Protection of Human Subjects (CPHS) has direct control over this matter at the University of Texas - Houston Medical School and, along with the FDA, approved waiver of consent. The CPHS is made up of individuals from many different backgrounds, who review all studies involving human subjects in an effort to protect the patient and make certain that as much as possible has been done to ensure safety, privacy and confidentiality, emotional health and many other social considerations.

Patients were enrolled in the study in one of three ways. First, patients gave their own informed consent if they were able. Second, if a patient was unable to consent, then upon arrival in the emergency department the hospital staff tried to reach a family member. If this was successful, the family was asked to provide informed assent. Informed assent is very similar to informed consent, but instead of the patient receiving information and agreeing or not agreeing to the treatment offered, the family member acts for the patient. Third, if a family member was not located quickly enough for the drug to have a chance of working, the patient was enrolled under the FDA regulations permitting the use of waiver of consent. The effort to locate and inform family continued even after the patient had been enrolled in the study and received the first dose of the drug. When found, family members were given the opportunity to choose whether their relative stayed in the study.

The investigational drug that was tested is called Hu23F2G (LeukArrest TM). ICOS (Bothell, Washington) is the manufacturer of the drug and the sponsor of the study. ICOS is also responsible to the FDA. Hu23F2G is known to act on white blood cells, which may stop them from causing damage to the body's major organs (lungs, heart, kidney, liver) following trauma. Most often trauma occurs because of motor vehicle accidents, falls, stabbings, gunshots, etc. In order to determine the safety and effectiveness of this new drug, researchers studied 150 trauma patients at 11 trauma centers throughout the United States. In this clinical trial, some patients received one of two different doses of the drug, Hu23F2G, along with standard care for their injury, and some received standard care only.

Enrollment into the study was completed on January 26, 1999. Information from all of the trauma centers where the study was carried out indicates that 14% of patients were able to sign their own consent. Fifty-three percent (53%) had a family member provide informed assent and 33% were enrolled with waiver of informed consent. At the University of Texas - Houston Medical School/Hermann Hospital, 28 patients were enrolled into the study from April 1998 to the end of January 1999. One patient was able to sign their own consent, 15 had a family member provide informed assent, and 12 patients were enrolled using the waiver of informed consent.

The average patient was 36 years old; males were enrolled twice as often as females. The majority of the patients were Caucasian (58%), followed by African American (25%) and other races (17%). At University of Texas - Houston Medical School/Hermann Hospital the average patient was 40 years old, and 16 males and 12 females were enrolled. The majority of patients were Caucasians (57%), followed by other races (32%) and African American (11%).

Preliminary analysis of the study has been performed. Hu23F2G appears to be safe in this patient population. Overall a total of 11 patients (7%) died in the study. The death rate was 10% in patients who received standard of care alone and 6% in patients who received Hu23F2G. Although there was little difference in patient results, there was a suggestion that those patients who received the higher dose of Hu23F2G had fewer heart and lung failures compared with those patients who received standard care only. Further analyses of the data are underway.

Any questions about this study should be directed to Frederick A. Moore, M.D., at (713) 500-7228.

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Associated Press

Joe Valentino, left, and David Harper pose for the camera as they celebrate Mardi Gras while strolling through the streets of the French Quarter in New Orleans.

Southern Louisiana is heavily Catholic.

This year's later-than-usual Mardi Gras, coinciding with spring break for many colleges and 80-degree weather, was expected to produce a record crowd in excess of the million or so that usually jam New Orleans and its suburbs.

"This is my sixth Mardi Gras, and it's the largest crowd I've seen," Pennington said. "I'm sure we'll set a record. I'd estimate we have well over a million, maybe a million and a half people on the streets."

The narrow streets of the French Quarter were jammed by midmorning as people strolled through ankle-deep trash or clustered under balconies to grab beads dropped from above.

Booze flowed, with revelers sipping from plastic cups as they walked, and strangers danced to music blaring from bars or posed with each other for pictures.

"I've seen things I never saw before, ate things I never ate before, and drank things that I'm sure will be lethal," said Larry Ward, 34, of Detroit. "But I'll sure die happy."

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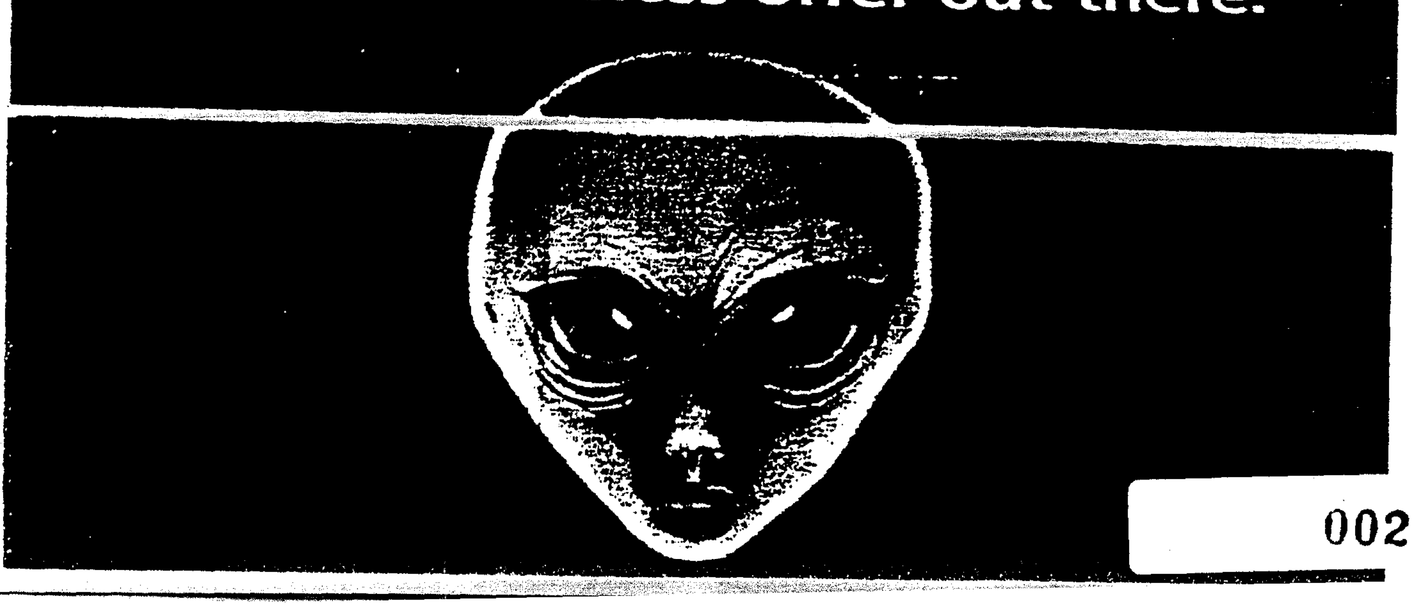

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